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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,728	09/22/2003	Donald J. Kerrish	61404-018	4677

7590 06/14/2005

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EXAMINER	
MCINTOSH III, TRAVISS C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/665,728	KERRISH ET AL.	
	Examiner	Art Unit	
	Traviss C. McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to methods of preparing pellets or tablets comprising a sustained release formulation of ribavirin, classified in class 514, subclass 43.

II. Claims 7-8, drawn to sustained release capsules or tablets comprising ribavirin, classified in class 424, subclass 457.

III. Claims 9-13, drawn to methods of forming a composition comprising free flowing ribavirin particles, classified in class 514, subclass 43.

IV. Claims 14-19, drawn to a free flowing ribavirin composition, classified in class 424, subclass 400+.

V. Claim 20, drawn to methods of treating subjects from an undisclosed disease by administering a sustained release dosage of ribavirin, classified in class 514, subclass 43.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another materially different process, such as by using the dosage system of Chen et al. (US 5,837,379).

Inventions I and III are unrelated. The invention of group I is drawn to making a sustained release dosage of ribavirin, and the invention of group III is drawn to making flowable ribavirin particles, which are seen to be divergent compositions. As such, the methods of making these different compositions are also seen to be divergent. It is noted that a search in the prior art for group I would not be required for group III, and a reference anticipating or rendering obvious either of the groups would not be expected to anticipate or render obvious the other.

Inventions I and IV are unrelated. The invention of group I is drawn to making a sustained release dosage of ribavirin, which is different than the invention of group IV, which is drawn to a free flowing ribavirin composition. The methods of making the composition as set forth in group I would not make the composition as set forth in group IV. It is noted that a search in the prior art for group I would not be required for group IV, and a reference anticipating or rendering obvious either of the groups would not be expected to anticipate or render obvious the other.

Inventions I and V are related as process of making and process of using the product. The methods of groups I and IV do not utilize the same methodological steps and they provide different outcomes. Moreover, the method of using the product of group V is not limited to any specific type of sustained release composition, and the invention of group I is drawn to making pellets, as such, if the examiner found a reference anticipating group V it would not be expected to render obvious or anticipate the invention of group I.

Inventions II and III are unrelated. The invention of group II is drawn to a sustained release capsule of tablet of ribavirin, and the invention of group III is drawn to making flowable ribavirin particles. The methods of making the composition of group III would make a different

composition than that of group II. It is noted that a search of the prior art for group II would not be required for group III, and a reference anticipating or rendering obvious either of the groups would not be expected to anticipate or render obvious the other.

Inventions II and IV are unrelated. The invention of group II is drawn to a sustained release dosage of ribavirin, and the invention of group IV is drawn to a free flowing ribavirin composition, which is different than a sustained release dosage. It is noted that a search of the prior art for group II would not be required for group IV, and a reference anticipating or rendering obvious either of the groups would not be expected to anticipate or render obvious the other.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of using the product as claimed can be practiced with another materially different product. The method of use of group V is drawn to "treating a subject", and does not disclose what is being treated. As such, the method of group V can be practiced with another materially different product, such as using aspirin as set forth in US 4,970,081.

Inventions III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the

process as claimed can be used to make a materially different product, such as by using another active agent in place of ribavirin, such as using the compounds in US 6,093,747. Moreover, it is noted that the invention of group IV requires various agents which are not added in the method of group III, as such, a reference anticipating or rendering obvious one group would not be expected to anticipate or render obvious the other group.

Inventions III and V are related as process of making and process of using the product> They do not utilize the same methodological steps and they provide different outcomes. Moreover, the method of using the product of group V is not limited to any specific type of sustained release composition, and the invention of group III is drawn to making a free flowing composition, and as such if the examiner found a reference anticipating group V it would not be expected to render obvious or anticipate the invention of group III.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of using the product as claimed can be practiced with another materially different product. The method of use of group V is drawn to "treating a subject", and does not disclose what is being treated. As such, the method of group V can be practiced with another materially different product, such as using aspirin as set forth in US 4,970,081.

Because these inventions are distinct for the reasons given above and the search required for one Group is not required for another Group, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection

are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh III
June 9, 2005

James O. Wilson
Supervisory Patent Examiner
Art Unit 1623